FDA OKs Merck drug, first in new cancer drug class (Update)

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In this Thursday, Feb. 28, 2013 file photo, a Merck logo is placed on scientist's lab coat in West Point, Pa. The Food and Drug Administration on Thursday, Sept. 4, 2014 said it has granted accelerated approval to Merck's Keytruda, for treating melanoma that's spread or can't be surgically removed, in patients previously treated with another drug. (AP Photo/Matt Rourke, File)

Merck & Co. on Thursday won the first U.S. approval for a new kind of cancer drug with big advantages over chemotherapy and other older cancer treatments.

The Food and Drug Administration said it has granted accelerated approval to Merck's Keytruda, for treating melanoma that's spread or can't be surgically removed, in patients previously treated with another melanoma drug called Yervoy.

Experts called the news "game-changing" for patients with the deadly skin cancer, which is becoming more common and kills nearly 10,000 Americans each year.

Keytruda, a genetically engineered drug known chemically as pembrolizumab, is part of a hot, promising new class of antibody-based drugs. They work by taking a brake off the immune system so it can better recognize and attack cancer cells.

"Ninety percent of patients have basically no side effects," Dr. Antoni Ribas, a researcher and professor at UCLA's Jonsson Comprehensive Cancer Center who was the lead investigator of a crucial study of Keytruda, told The Associated Press in an interview.

By comparison, most patients getting chemotherapy suffer with nausea, vomiting and hair loss.

In addition, Ribas said, Keytruda and other "immune-therapy" drugs appear likely to work against many more types of cancer than older drugs, and in a much higher percentage of patients.

In a study funded by Merck, which is based in Whitehouse Station, New Jersey, one-third of the 600 patients participating benefited from the drug, with 62 percent of those alive after 18 months.

Chemotherapy drugs have an average survival of about nine months, while some newer cancer drugs on average keep patients alive for 11 to 15 months, noted Ribas, who serves as an adviser to Merck but said he

donates all payments to UCLA.

This undated product image provided by Merck & Co., Inc. shows packaging for its Keytruda cancer drug. The Food and Drug Administration on Thursday, Sept. 4, 2014 said it has granted accelerated approval to Keytruda, for treating melanoma that's spread or can't be surgically removed, in patients previously treated with another drug. (AP Photo/Merck & Co., Inc.)

"This is just the start," Ribas said, adding that earlier tries at immune therapy for cancer typically helped only 5 percent to 10 percent of patients.

The average overall survival rate for Keytruda hasn't been determined yet, as most patients in the study are still being followed.

Merck's drug is the first in the class of what's called anti-PD-1 drugs approved in the U.S.

"This drug represents a major step forward," Dr. Louis M. Weiner, a spokesman for the American Association for Cancer Research, said in a statement. "It is an effective immunotherapy (but) not a general immune stimulant. It attacks a specific mechanism employed by some cancers to actively evade immune destruction."

Bristol-Myers Squibb Co. and a partner have a drug similar to Keytruda, called Opdivo, which was approved in Japan in July. They are seeking U.S. approval for it.

Merck said Keytruda will cost about $12,500 per month for many patients—similar to the price of many other new cancer drugs—and on average treatment lasts for just over six months.

The drug did have serious, immune-related side effects in a small number of patients, including hepatitis, colitis, thyroid problems and kidney inflammation. It's administered every three weeks through a slow intravenous drip—until the cancer progresses or the patient has intolerable side effects.

One study participant, 49-year-old Rich Murphy of Marshfield, Massachusetts, said that after about five rounds of treatment with Keytruda in 2012, he stopped taking medicines and was still cancer-free at his latest checkup 2 ½ months ago.

"I owe my life to that drug. There's no question about it," Murphy, a real estate agent, said in an interview.

He had about 15 melanoma tumors under the skin throughout his torso, and after being diagnosed in 2008, underwent multiple rounds of

radiation and surgery, plus chemotherapy. He then took Bristol-Myers' Yervoy, but it stopped working after several months.

Once he started on Keytruda, Murphy said, the only side effect he had was dry skin.

Tim Turnham, executive director of the Melanoma Research Foundation, called Keytruda's approval "a tremendous step forward for the melanoma patient community."

"This is the most promising and positive patient response to a melanoma treatment to date," he said in a statement, but cautioned that it won't work in all late-stage melanoma patients—the goal of ongoing research.

Merck, Bristol-Myers and rivals including Astra-Zeneca PLC and the Roche Group all are running multiple studies of anti-PD-1 drugs, used alone or in combination with other medicines, for treating a variety of cancers. Those include head and neck cancer, bladder and gastric cancers and non-small cell lung cancer, as well as advanced melanoma.

In after-hours trading, Merck shares rose 22 cents to $60.30. They had dipped 40 cents in regular trading as the broader markets all declined.